

Theranova 400

DESIGNED FOR:
HDx

MEMBRANE:
MCO (PAES/PVP, BPA-free)

HDx THERAPY ENABLED BY THERANOVA*

HDx therapy delivers expanded haemodialysis, which is the next evolution in haemodialysis, as it targets the efficient removal of large middle molecules (25 kDa to < 60 kDa).¹ Indeed, many of them are linked to the development of inflammation, cardiovascular disease, and other co-morbidities in dialysis patients.² With HDx therapy, **Theranova** provides superior removal of large middle molecules compared with HD and HDF modalities and it does so using regular HD workflow and infrastructure.³

HDx therapy is enabled by the **Theranova** dialyser series, which features an innovative membrane design that combines a permeability higher than that of regular high-flux dialysers with effective selectivity for large proteins.^{4,5}

PROVIDE EXPANDED HD, RETAIN HD SIMPLICITY

- Markedly greater clearances and intradialytic reduction ratios for middle molecules than regular HD – at ordinary blood flow rates³
- Superior removal of large middle molecules compared to HD and HDF modalities³
- Limited albumin removal of between 1 and 4 grams per session³
- Compatible with any HD monitor^{6,7} and with standard dialysis

WITH VANTIVE'S LATEST DIALYSER INNOVATION, COMING CLOSER TO THE NATURAL KIDNEY^{4,5}

- High permeability to large middle molecules
- Effective selectivity by size exclusion
- Augmented internal filtration
- Similar retention of endotoxins to other dialysis membranes of the same material⁸

CLINICAL EFFICIENCY AND PATIENT-REPORTED OUTCOMES

- Pre-dialysis levels of beta 2 microglobulin and kappa and lambda free light chains were reduced after 3 and 6 months with HDx therapy using the **Theranova** dialyser in a multi-centric observational study of 41 HD patients.^{9,†}
- Restless Leg Syndrome criteria are reduced approximately 50% after 6 months for prevalent HD patients in a large observational study by Vantive.^{11,‡} A smaller before-after study found no difference in patient-reported symptom burden.^{10,‡‡}

* Do not use **Theranova** dialysers in HDF or HF mode

† Based on data presented in a congress abstract – see reference for details.

‡‡ Based on data presented in a congress abstract – see reference for details. Restless leg syndrome was only one of several secondary endpoints.

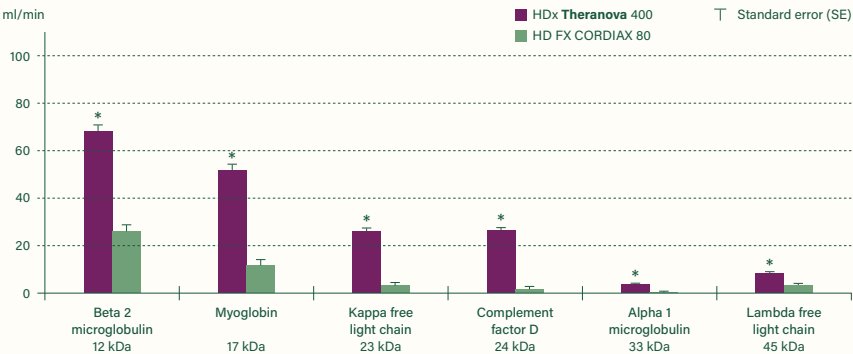


CLINICAL PERFORMANCE³

OVERALL CLEARANCE HDx vs. HD

HDx with TheraNova 400 dialyser
HD with latest generation high-flux dialyser
 $Q_b = 300$ ml/min – Treatment Time = 4 h (Mean) – n = 19

* p<0.001 vs high-flux HD

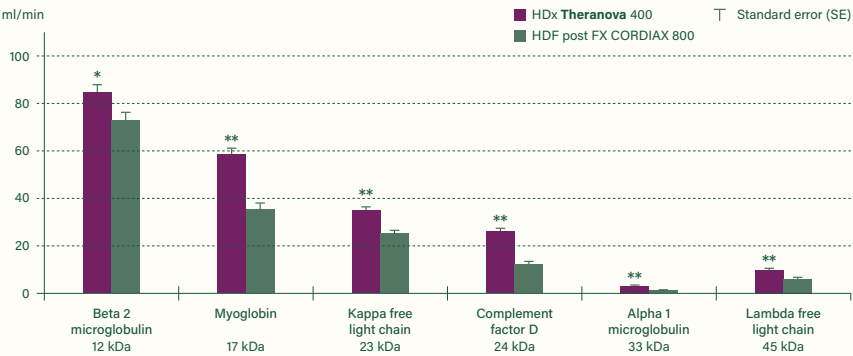


Modified after Kirsch AH, et al. Performance of hemodialysis with novel medium cut-off dialyzers. Nephrol Dial Transpl 2017; 32(1):165-72.

OVERALL CLEARANCE HDx vs. HDF

HDx with TheraNova 400 dialyser
HDF with latest generation high-flux dialyser for HDF
 $Q_b = 400$ ml/min – Treatment Time = 4.4 h – Vconv = 24L (Mean) – n = 20

* p<0.01 vs HDF
** p<0.001 vs HDF

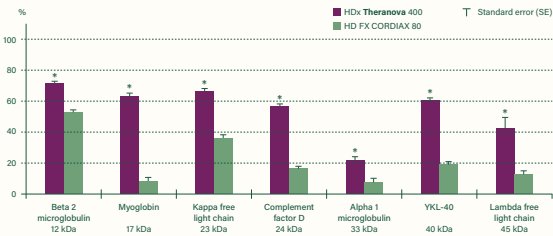


Modified after Kirsch AH, et al. Performance of hemodialysis with novel medium cut-off dialyzers. Nephrol Dial Transpl 2017; 32(1):165-72.

REDUCTION RATIO HDx vs. HD

HDx with TheraNova 400 dialyser
HD with latest generation high-flux dialyser
 $Q_b = 300$ ml/min – Treatment Time = 4 h (Mean) – n = 19

* p<0.001 vs high-flux HD

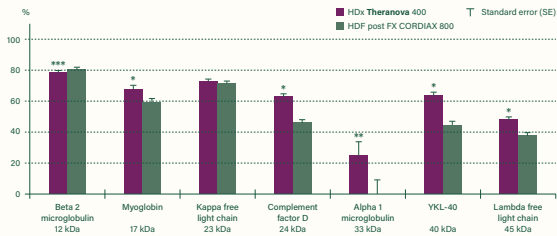


Modified after Kirsch AH, et al. Performance of hemodialysis with novel medium cut-off dialyzers. Nephrol Dial Transpl 2017; 32(1):165-72.

REDUCTION RATIO HDx vs. HDF

HDx with TheraNova 400 dialyser
HDF with latest generation high-flux dialyser for HDF
 $Q_b = 400$ ml/min – Treatment Time = 4.4 h – Vconv = 24L (Mean) – n = 20

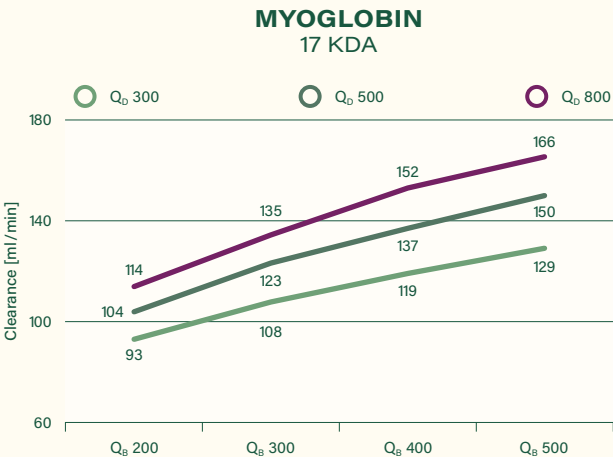
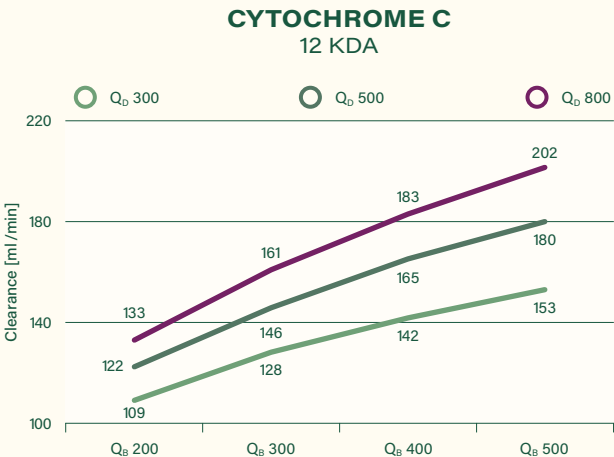
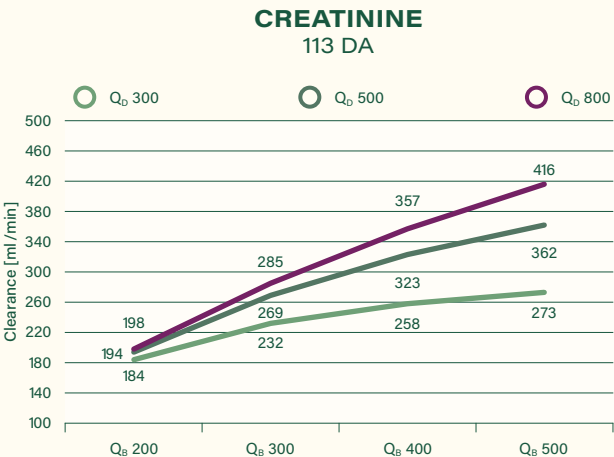
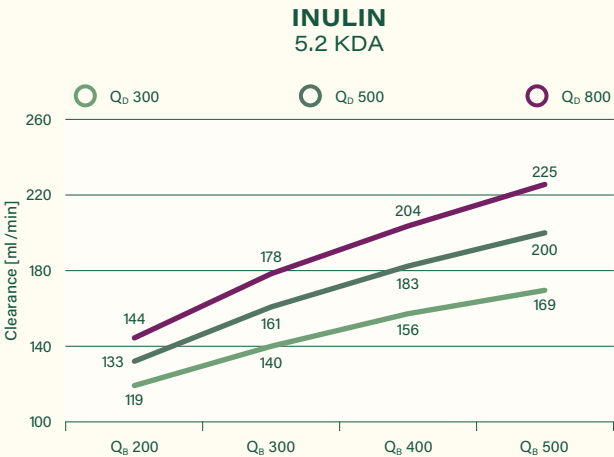
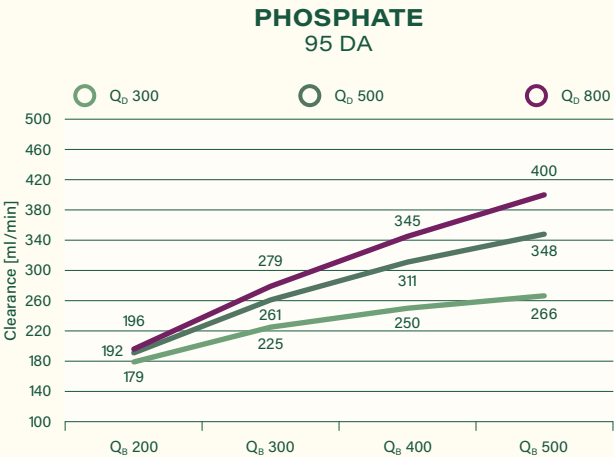
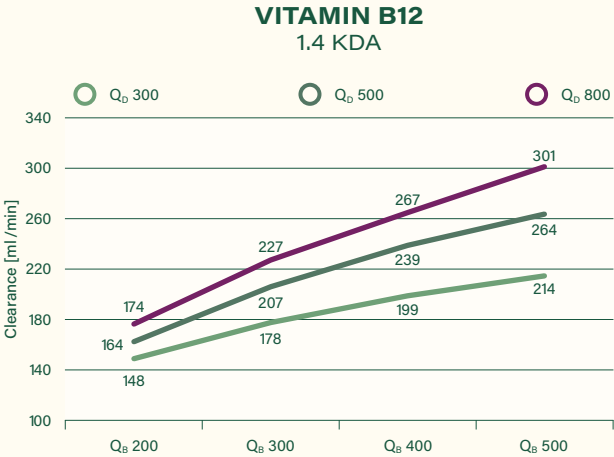
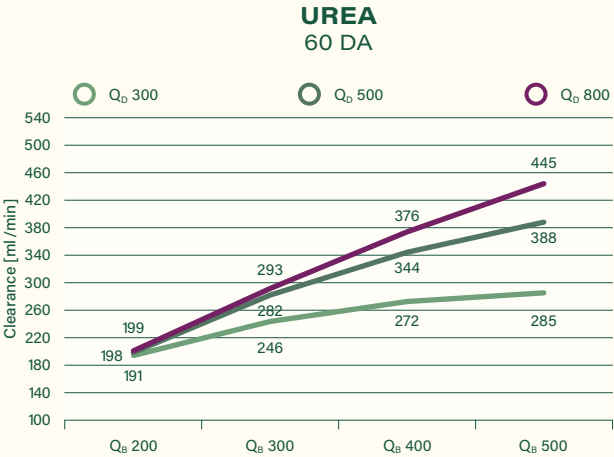
* p<0.001 vs HDF
** p<0.01 vs HDF
*** p<0.05 vs HDF



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IN VITRO CLEARANCES

In vitro clearances are indicated in (ml/min) ± 10%



THERANOVA 400 Specifications

MATERIALS	THERANOVA 400
Membrane	Medium cut off Polyarylethersulfone and Polyvinylpyrrolidone blend BPA-free
Potting	Polyurethane (PUR)
Housing	Polycarbonate (PC)
Gaskets	Silicone rubber (SIR)
Protection caps	Polypropylene (PP)
Sterilisation	Steam (inside-out)
Sterile barrier	Tyvek

SPECIFICATIONS	
UF-Coefficient (mL/(h*mmHg))*	48
KoA urea*	1482
Blood Compartment volume (mL)	91
Minimum recommended priming volume (mL)	300
Maximum TMP (mmHg)	600
Recommended Q _B (mL/min)	200-600
Storage conditions	<30°C (or <86°F)
Units per box	24
Gross/net weight (g)	229/170

MEMBRANE	
Effective Membrane Area (m²)	1.7
Fiber inner diameter (µm)	180
Fiber wall thickness (µm)	35
Sieving profile – before blood exposure ⁴	
MWCO (cut-off) [kDa]	56 +/-3
MWRO (rentation onset) [kDa]	9.4 +/- 0.2

SIEVING COEFFICIENTS*	
Vitamin B12 (1,4 kDa)	1.0
Inulin (5,2 kDa)	1.0
β ₂ -microglobulin (11,8 kDa)	1.0
Myoglobin (17 kDa)	0.9
Albumin (66,4 kDa)	0.008

* According to EN 1283/ISO 8637:
– UF-Coefficient: measured with bovine blood, Hct 32%, Pct 60g/L, 37°C
– KoA urea: calculated at Q_B=300 mL/min, Q_D=500mL/min, UF=0 mL/min
– Sieving coefficients: measured with human plasma, Q_B=300 mL/min, UF=60 mL/min
– Clearances In-Vitro: measured at UF=0 mL/min, ±10% (±20% Cyt. C, ±30% Myo.)

CLEARANCES IN VITRO (mL/min)*	THERANOVA 400
Urea (60 Da) (Q_B-Q_D, mL/min)	
200/500	198
300/500	282
400/500	344
400/800	376
500/800	445
Phosphate (95 Da)	
200/500	192
300/500	261
400/500	311
400/800	345
500/800	400
Creatinine (113 Da)	
200/500	194
300/500	269
400/500	323
400/800	357
500/800	416
Vitamin B12 (1,4 kDa)	
200/500	164
300/500	207
400/500	239
400/800	267
500/800	301
Inulin (5.2 kDa)	
200/500	133
300/500	161
400/500	183
400/800	204
500/800	225
Cytochrome C (12 kDa)	
200/500	122
300/500	146
400/500	165
400/800	183
500/800	202
Myoglobin (17 kDa)	
200/500	104
300/500	123
400/500	137
400/800	152
500/800	166

1. Ronco C, et al. *The rise of Expanded Hemodialysis*. Blood Purif 2017; 44:I-VIII.
2. Hutchison CA, et al. *The Rationale for Expanded Hemodialysis Therapy (HDx)*. Contrib Nephrol 2017; 191:142-52.
3. Kirsch AH, et al. *Performance of hemodialysis with novel medium cut-off dialyzers*. Nephrol Dial Transpl 2017; 32(1):165-72.
4. Boschetti-de-Fierro A, et al. *MCO membranes: Enhanced Selectivity in High-Flux Class*. Scientific Reports 2015; 5:18448.
5. Zweigart C, et al. *Medium cut-off membranes – closer to the natural kidney removal function*. Int J Artif Organs 2017; 40(7):328-334.
6. Vantive. Data on file. *Theranova Limited Controlled Distribution Report*. 2016.
7. Vantive. *Theranova 400/500 Instructions For Use*. N50 648 rev 003, 2017-05-29.
8. Schepers E, Glorieux G, Elout S, et al. *Assessment of the association between increasing membrane pore size and endotoxin permeability using a novel experimental dialysis simulation set-up*. BMC Nephrology. 2018; 19:1.
9. Cantaluppi V, et al. *Removal of large-middle molecules on expanded hemodialysis (HDx): a multicentric observational study of 6 months follow-up*. ASN 2018 Kidney Week Abstract TH-PO357.
10. Krishnasamy R, et al. *Trial evaluating mid cut-off value membrane clearance of albumin and light chains in hemodialysis patients (REMOVAL-HD): a safety and efficacy study*. ASN 2018 Kidney Week Abstract TH-PO353.
11. Sanabria M, et al. *Quality of life reported by patients with expanded hemodialysis by the Theranova dialyzer in RTS Colombia*. ASN 2018 Kidney Week Abstract TH-PO296.

The products meet the applicable provisions of Annex I (Essential Requirements) and Annex II (Full quality assurance system of the Council Directive 93/42/EEC of 14 June 1993, amended by Directive 2007/47/EC).

For safe and proper use of the device, please refer to the Instructions for Use



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